Unaffiliated Investigator Agreement

PLEASE COMPLETE AND SIGN THE ATTACHED UNAFFILIATED INVESTIGATOR AGREEMENT (UIA) FORM IMMEDIATELY.

PLEASE FAX THE COMPLETED AND SIGNED COPY OF THE UIA BACK TO HEALTH STUDIES BRANCH, CDC (Ciguatera Diagnostic Method Study) AT FAX NUMBER: 770-488-3450 (voice: 770-488-3410)

MAIL THE ORIGINAL COMPLETED/SIGNED UIA FORM WITH THE OTHER STUDY DOCUMENTS TO THE FOLLOWING ADDRESS:

ATTN: Ciguatera Diagnostic Method Study
Robert Dickey, PhD
FDA, Gulf Coast Seafood Laboratory
1 Iberville Drive, PO Box 158
Dauphin Island, AL 36528-0158

Phone: (251) 694-4480 ext 249
Fax: (251) 694-4477

ONCE THE ORIGINAL FORM IS SIGNED AT CDC INSTITUTIONAL REVIEW BOARD OFFICE, A COPY WILL BE MAILED BACK TO THE CDC INVESTIGATOR TO KEEP A COPY OF THE SIGNED FORM WITH THE PROTOCOL. THE CDC INVESTIGATOR WILL THEN FORWARD A COPY TO YOU FOR YOU TO KEEP ON FILE.

Unaffiliated Investigator Agreement

Name of Institution Providing Institutional Review Board Oversight:
Centers for Disease Control and Prevention (CDC)

OHRP Federal-wide Assurance Number: **FWA00001413**

Unaffiliated Investigator:
Name: _____ Degree(s): _____
(Last) (First) (Middle Initial)

1. The above-named Unaffiliated Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (http://www.med.umich.edu/irbmed/ethics/belmont/BELMONTR.HTM or other internationally recognized equivalent; see B1 of FWA Terms for institutions outside the United States); 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm or other internationally recognized equivalent, see B3 of FWA Terms for institutions outside the United States); 3) the Federal-wide Assurance (FWA) referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects (http://www.cdc.gov/od/ads/hsr2.htm).

2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

3. The Investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human subjects.

4. The Investigator will abide by all determinations of the Institutional Review Board/Institutional Ethics Committee (IRB/IEC) designated under the above Assurance and will accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities.

5. The Investigator will complete any educational training required by the Institution and/or the IRB/IEC prior to initiating research covered under this Agreement.

6. The Investigator will report promptly to the IRB/IEC any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subject.

7. The Investigator will report immediately to the IRB/IEC any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

8. The Investigator will obtain, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under DHHS and FDA regulations (or other international or national equivalent) and stipulated by the IRB/IEC. The Investigator acknowledges and agrees to cooperate in the IRB/IEC's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the IRB/IEC in a timely fashion.

9. In conducting research involving FDA-regulated products, the Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1) and 812 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1)

10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB/IEC.

11. Emergency medical care may be delivered without IRB/IEC review and approval to the extent permitted under applicable Federal regulations and State law. However, data and information obtained as a result of emergency medical care may not be included as part of federally-supported or –conducted research.

12. This Agreement does not preclude the Investigator from taking part in research not covered by the Agreement.

13. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _____
Name of Institution: _____
Address: _____ Phone #: _____
_____
(City) *(State/Province)* *(Zip/Country)*

CDC IRB/IEC Institutional Official:

Signature: _____ **Date** _____

Name/Degrees: John R. Livengood, MD, MPhil
Title: Deputy Associate Director for Science
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